IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 7,482,128 B2	)	Confirmation No. 8347
Issued: January 27, 2009	)	Group Art Unit: 1641
By: Jensen, Wayne A. Hunter, Shirley W. Sverlow, Karen Andrews, Janet S.	)	Examiner: Cheu, Changhwa J.
Serial No.: 10/550,563	)	REQUEST FOR CERTIFICATE OF CORRECTION FOR USPTO MISTAKES
Filed: August 14, 2006	)	
Atty. File No.: DI-13-C6-PUS	)	
For: "NOVEL ANTI-FELINE ALBUMIN ANTIBODIES"	)	

Commissioner for Patents
ATTN: Certificate of Correction Branch
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This is a request for a Certificate of Correction under 37 C.F.R. 1.322(a). Attached is Form PTO-1050. The corrections requested are as follows:

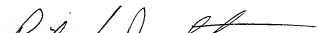
Column 43, line 9, please replace "fetid" with –felid--.
Column 44, line 3, please replace "feud" with –felid--.

Support for the above corrections to the claims can be found in Applicants' Amendment and Response, filed October 15, 2008, which was acknowledged by the Examiner in the Notice of Allowability, dated November 17, 2008.

Applicants do not believe any fees are due with this correspondence, but in the event fees are due, please debit Deposit Account No. 19-1970.

Respectfully submitted,

Dated: May 14, 2009

By: 

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US007482128B2

(12) United States Patent
Jensen et al.

(10) Patent No.: US 7,482,128 B2
(45) Date of Patent: Jan. 27, 2009

(54) **ANTI-FELINE ALBUMIN ANTIBODIES**

(75) Inventors: **Wayne A. Jensen**, Wellington, CO (US); **Shirley Wu Hunter**, Fort Collins, CO (US); **Karen Sverlow**, Dixon, CA (US); **Janet S. Andrews**, Westminster, CO (US)

(73) Assignee: **Heska Corporation**, Loveland, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/550,563**

(22) PCT Filed: **Mar. 25, 2004**

(86) PCT No.: **PCT/US2004/009135**

§ 371 (c)(1),
(2), (4) Date: **Aug. 14, 2006**

(87) PCT Pub. No.: **WO2004/084841**

PCT Pub. Date: **Oct. 7, 2004**

(65) **Prior Publication Data**

US 2006/0281131 A1 Dec. 14, 2006

(51) **Int. Cl.**
G01N 33/53 (2006.01)

(52) **U.S. Cl.** **435/7.1**; 435/7.2; 435/7.91; 435/7.92; 436/516; 436/518

(58) **Field of Classification Search** **435/7.1**, 435/7.2, 7.91, 7.92; 436/516, 518
See application file for complete search history.

(56) **References Cited**

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* cited by examiner

Primary Examiner—Mark L Shibuya
Assistant Examiner—Jacob Cheu

(57) **ABSTRACT**

The present invention provides isolated monoclonal antibodies that selectively bind albumin from animals. Also provided are methods using such antibodies for the detection of early renal disease in animals. The method includes the steps of (a) obtaining a sample from an animal to be tested; (b) contacting the sample with an antibody having a greater avidity for feline albumin than for other proteins or components in the sample; (c) detecting the complex formed by the antibody and albumin; and (d) determining the amount of albumin in the sample from the amount of antibody-albumin complex detected. An amount of albumin in the range of from 10 μg/ml to about 300 μg/ml indicates the presence of early renal disease.

2 Claims, No Drawings

Although the invention has been described with reference to the presently preferred embodiments, it should be understood to those skilled in the art that various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. An isolated monoclonal antibody that selectively binds albumin from a felid or a canid, wherein said antibody binds the same epitope recognized by the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

2. A kit comprising:

(a) an isolated monoclonal antibody that selectively binds albumin from a felid or canid, wherein said antibody binds the same epitope recognized by the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425); and

(b) a means for detecting the amount of albumin in a sample collected from a felid or canid, wherein said means detects albumin in a range from about 10 μg/ml to about 50 μg/ml.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Jensen, Wayne A.
Hunter, Shirley Wu
Sverlow, Karen
Andrews, Janet S.

Serial No.: 10/550,563

Confirmation No.: 8347

Filed: September 27, 2005

Atty. File No.: DI-13-C6-PUS

For: "NOVEL ANTI-FELINE ALBUMIN ANTIBODIES"

Group Art Unit: 1641

Examiner: Cheu, Changhwa J

Customer No.: 26949

AMENDMENT AND RESPONSE

CERTIFICATE OF ELECTRONIC TRANSMISSION

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING ELECTRONICALLY TRANSMITTED VIA USPTO EFS, ADDRESSED TO MAIL STOP AF, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, THIS 15 DAY OF OCTOBER 2008.

HESKA CORPORATION

By: Susan Gordon

Susan Gordon

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COPY

Dear Sir:

In response to the Final Office Communication mailed from the United States Patent and Trademark Office (USPTO) on January 29, 2008, Applicants filed a Notice of Appeal on July 29, 2008, along with a three-month extension of time. On October 14, 2008, Applicants conducted a telephonic interview with Examiner Cheu during which they discussed Applicant's recent deposit of a hybridoma cell line with the ATCC deposit. During the interview, the Examiner agreed that, in view of the ATCC deposit, Applicants could submit amended claims in response to the Final Office Communication. Thus, in lieu of filing an Appeal Brief, Applicants submit herewith a response, containing amended claims, to the Final Office Action.

Applicants also submit herewith a request for a one-month extension extending the time for response from September 29, 2008 to October 29, 2008.

Please amend the Application as follows:

IN THE CLAIMS

Please cancel claims 32, 33 and 38 without prejudice to or disclaimer of the subject matter therein, and amend claims 34-37 and 39-40 as follows.

1-33. (Canceled)

34. (Currently amended) An isolated antibody that selectively binds albumin from a felid or a canid, wherein said antibody inhibits the binding of said albumin by the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

35. (Currently amended) The isolated antibody of claim 34, wherein said antibody binds the same epitope recognized by the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

36. (Currently amended) The isolated antibody of claim 34, wherein said antibody is the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

37. (Currently amended) A kit comprising:

(a) an isolated antibody that selectively binds albumin from a felid or canid, wherein said antibody inhibits the binding of said albumin by the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425); and

(b) a means for detecting the amount of albumin in a sample collected from a felid or canid, wherein said means detects albumin in a range from about 10 µg/ml to about 50 µg/ml.

38. (Canceled)

39. (Previously presented) The kit of claim 37, wherein said antibody binds the same epitope as the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

40. (Previously presented) The kit of claim 37, wherein said antibody is the monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498 (MAb H425).

REMARKS

Claims 34-37 and 39-40 have been amended so that monoclonal antibody H425 is identified as being a monoclonal antibody produced by the hybridoma cell line having ATCC Accession No. PTA-9498.

I. Correction of Inventors under 37 CFR §1.48(b)

In the Office Communication mailed January 29, 2008, the Examiner stated that Applicants' previous request to correct inventorship under 37 CFR 1.48(b) was not considered since Applicants failed to file a separate petition for removal of inventors. Applicants note that a separate Petition to Correct Inventorship Under 37 CFR 1.48(b) was filed with the USPTO on February 8, 2008.

II. ATCC Deposit of Antibody H425

The Examiner has rejected claims 34-37 and 39-40, stating that the H425 antibody is required to practice the claimed invention, and as such, it must be available to the public or obtainable by a repeatable method set forth in the specification. The Examiner further states that deposit of the cell line / hybridoma which produces the H425 antibody would satisfy the requirements of 35 USC § 112, first paragraph, and would thus render claims 34-37 and 39-40 allowable.

Applicants note that the hybridoma cell line that produces monoclonal antibody H425 has been deposited with the ATCC, said cell line being assigned the Patent Deposit Designation PTA-9498. Applicants are submitting herewith a copy of the Certificate of Deposit verifying this deposit, as well as a Declaration stating that the hybridoma cell line deposited with the ATCC is the hybridoma cell line that produces the monoclonal antibody identified as H425 in the instant specification. Consequently, Applicants have amended the claims so that reference to monoclonal antibody H425 has been replaced with the appropriate ATCC Accession Number. Applicants hereby state that all restrictions imposed by Heska Corporation ("depositor") on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. Patent Application Serial No. 10/550,563. In view of the above-mentioned deposit and the related amendments to the claims, Applicants request withdrawal of the rejection under 35 USC § 112, first paragraph.

CONCLUSION

All of the pending claims are believed to be in condition for allowance. In the event the Examiner has any questions regarding this Application, the Examiner is invited to contact the undersigned representative at (970) 493-7272 ext. 4174.

Respectfully submitted,

Dated: October 15, 2008

By: Richard J. Stern

Richard J. Stern, Ph.D.
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Heska Corporation
3760 Rocky Mountain Avenue
Loveland, Colorado 80538
Telephone: (970) 493-7272, ext. 4174
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RJS

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26949 7590 11/17/2008

HESKA CORPORATION
LEGAL DEPARTMENT
3760 ROCKY MOUNTAIN AVE
LOVELAND, CO 80538

EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/17/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,563	08/14/2006	Wayne A Jensen	DI-13-C6-PUS	8347

TITLE OF INVENTION: NOVEL ANTI-FELINE ALBUMIN ANTIBODIES AND METHODS OF DETECTING EARLY RENAL DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	02/17/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Notice of Allowability	Application No. 10/550,563	Applicant(s) JENSEN ET AL.
	Examiner JACOB CHEU	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/15/2008*.

2. ☒ The allowed claim(s) is/are *35 and 37 now renumbered as claims 1-2*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *10/28/2008* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Oath & Declaration:

2. It is noted one of the inventors in this application, i.e. Karen Sverlow, has changed the post office address. This *oath & declaration* is considered defect since no initial upon the new address can be found. Applicant is requested to submit a new *oath & declaration* to remedy the defect.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Stern on 10/28/2008.

The application has been amended as follows:

Please cancel claims 35-36 and 39-40.

Claim 34, line 1, after "isolated", add -- monoclonal --.

Claim 34, line 2, replace "inhibits the binding of said albumin" with -- binds the same epitope recognized --.

Claim 37, line 2, step (a), after "isolated", add -- monoclonal --.

Claim 37, line 3, replace "inhibits the binding of said albumin" with-- binds the same epitope recognized --.

The petition for removing inventors Thomas McDonald and Annika Weber is granted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641

PTO/SB/44 (09-07)
Approved for use through 08/31/2010, OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,482,128 B2

APPLICATION NO.: 10/550,563

ISSUE DATE : Jan. 27, 2009

INVENTOR(S) : Wayne A. Jensen; Shirley Wu Hunter; Karen Sverlow; Janet S. Andrews

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 43, line 9, please replace "fetid" with –felid–.
Column 44, line 3, please replace "feud" with –felid–.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Sheridan Ross P.C.
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.